FOOD DECLARATION OF PRODUCT COMPLIANCE

The Business Operator, established in the European Community:

ANSELL HEALTHCARE EUROPE N.V. RIVERSIDE BUSINESS PARK, BLOCK J BOULEVARD INTERNATIONAL 5 5B-1070 BRUSSELS

declares that the glove described hereafter:

HyFlex™ 11-423

Formerly known as Puretough™P3000

belonging to the "Elastomers & Rubber" category

is in conformity with the following provisions:

the EC-regulation 1935/2004 and the EC-regulation 2023/2006 related to
Good Manufacturing Practices (GMP) for Materials and Articles intended to come in contact with Foodstuffs (for more detailed information please also consult Ansell GMP Food Declaration).

All ingredients, starting monomers, additives used in manufacturing this glove comply with:
- any positive list
- any relevant SML(Specific Migration Limit) or restrictions as specified in the applicable EU food legislations.

France: Arrêté du 5 août 2020, relatif aux matériaux et objets en caoutchouc destines à entrer en contact avec des denrées alimentaires
Italy: D.M. 21/03/1973 Disciplina igienica degli imballaggi, recipienti, utensili, destinati a venire in contatto con le sostanze alimentari o con sostanze d'uso personale
Germany: BfR Empfehlung XXI (01.02.2023) Bedarfsgegenstände auf Basis von Natur- und Synthesekautschuk
Netherlands: Regeling Verpakkingen en Gebruiksartikelen (Warenwet), Hoofdstuk III, Rubberproducten Verpakkingen
Czech Republic: Vyhláška č. 38/2001 Sb. (Consolidated 2009-5-15) Annex 07: Elastomers and rubber products - list of materials
Slovakia: Výnos MPSR a MZSR z 9. júna 2003 č. 1799/2003 - 100, Annex 10
FDA Code of Federal Regulations, Title 21, Part 177, section 2600 (21 CFR 177.2600) - Rubber articles intended for repeated use

Regulation (EU) 2024/3190 - no Bisphenol A (BPA) or other hazardous bisphenols are intentionally added to the product formulation of Ansell food contact approved products. Based on a review of the raw materials and formulation information, the product is considered to be in line with the requirements of Regulation (EU) 2024/3190, as corrected by Commission Regulation (EU) 2026/250, specifically:

- Article 3 – Prohibition of the use of BPA: Bisphenol A is not used as an ingredient in product formulation.
- Article 4 – Prohibition on the presence of BPA in food contact materials and articles for which other bisphenols or bisphenol derivatives are used: No BPA is present as a result of the use of other bisphenols or bisphenol derivatives in the formulation.
- Article 5 – Prohibition of the use of hazardous bisphenols: No hazardous bisphenols, as defined under Regulation (EU) 2024/3190, are intentionally used in the product formulation.

This statement is based on current formulation knowledge and supplier information and applies to the product as manufactured under normal, controlled production conditions.

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Global migration data:

Type of foodstuffs - Testing conditions	Aqueous food	Alcoholic food *Simulant used: Ethanol 10%*	Acidic food *Simulant used: Acetic acid 3%*	Fatty food correction factor 1 *Simulant used: Olive oil*	Fatty food correction factor 2 *Simulant used: Olive oil*	Fatty food correction factor 3 *Simulant used: Olive oil*	Fatty food correction factor 4 *Simulant used: Olive oil*	Fatty food correction factor 5 *Simulant used: Olive oil*
2 hours/temp. 40°C	< 8 mg/dm²		> 8 mg/dm²					< 8 mg/dm²
10min/40°C								< 10 mg/dm²

Analytical tolerance for aqueous, alcoholic and acidic food simulant is 1mg/dm² and for fatty food simulant is 3mg/dm² as per EN 1186.

Storage instruction: Keep away from direct sunlight; store in a cool dry place and keep in the original packaging. Keep away from ozone sources. If gloves are properly stored, as indicated above, they won't lose their performances and won't change the glove characteristics significantly. If gloves could be affected by ageing or storage, the expiry date is mentioned on the packaging materials.

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Director - Regulatory affairs
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